

FEDERAL TRADE COMMISSION  
WASHINGTON, D. C. 20580

BUREAU OF  
CONSUMER PROTECTION

December 6, 1976

Mr. Horace R. Kornegay, President  
The Tobacco Institute, Inc.  
1776 K Street, N.W.  
Washington, D.C. 20006

Dear Mr. Kornegay:

Your recent letter, addressed to Russell Hatchl, Esq., which contained Prof. Arkin's observations on FTC Tobacco Research Laboratory Test #17, has been sent to me for response.

We note with satisfaction Prof. Arkin's comment on improvement of the legibility of our records and the significant decrease in the number of computational errors he detected--which now stands at 2. Considering that the total number of determinations in Test #17 approximated 15,000, our rate of error has been reduced from 0.04% to 0.01%. The two arithmetic errors which were noted by Prof. Arkin have been reexamined and found, when the figures were rounded off, to have had no effect in the final results.

With regard to the posting errors tabulated in appendix II, we acknowledge that in the case of monitors tested on 6/19, results listed for ports 18 and 19 were inadvertently reversed in entry. The recorded difference of 0.2 mg between these two monitors in this case was well within acceptable monitor variations. Moreover, since all monitors on each day's run are averaged, the order of listing makes no difference. The error (17.7 entered for 17.0) also falls within this category. The citations for 8/6, 8/14 do represent typographical errors in recording. It must be noted that the averages of TPM and Nicotine for all monitors on the two days in question (based on about 20 determinations) did fall well within the acceptable "stop limits." This could have been verified by reference to the Monitor summary sheets previously submitted to Prof. Arkin. The final entries in appendix II refer to inadvertent non-posting of determinations for two branded cigarettes. Again,

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the final computations were based on averages for over 100 specimens of each brand. Thus, the two for which data were not posted had no effect on the final results.

Prof. Arkin's appendix V, citing "impossible" results, merely reflects omission of the negative (-) sign for water--which was, however, restored when results were calculated.

Prof. Arkin's comments on discards and deletions were discussed in my August 6, 1975, letter. As noted there--

The Commission uses the Dixon Outrider Test to identify data which fall outside the 95% confidence limit. These data are then discarded before the averages are computed. The individual samples from discarded days should not be considered in the total number of deletions. (A day is deleted if the monitor results for that day fall outside the limits allowed by  $30/\sqrt{n}$ . Clearly, this is one of the main reasons for using monitor cigarettes.) Furthermore, samples which have been dropped or otherwise lost during the analyses are not considered deletions. They are marked and may generally be distinguished from deleted samples by the absence of some or all of the data entries on the assay card. With these facts in mind, of approximately 5000 samples tested (in 1974), there remained only 252 which were deleted--giving a rate of 5.4% as predicted by the Dixon Outrider Test.

The data for 1975 are similar. Of the 1111 specimens discarded during this test, 896 were lost due to an entire day's run being deleted, since the monitor average for these days fell beyond the established "stop limits." (As previously discussed with Dr. Spears at the January 1974 meeting, the FTC monitor standard is based on the TPM and Nicotine averages obtained from not less than 700 randomly chosen monitors evaluated each time a new lot of monitors is received.) After averaging, aberrant results for monitors were obtained on 9 days. Accordingly, results for all branded cigarettes smoked during those days were discarded. The discards totaled 896 specimens, which, plus the two previously noted as inadvertently not posted, leaves a

remainder of 213 deletions. Of these, 53 were lost during testing and were irretrievable. Subtracting the above, we are left with the final 160 which were discarded because analytical results fell outside the limits allowed by the Dixon Outrider Test. Samples which were in this latter category were so identified by lining out on the summary sheets. This procedure is used since the Outrider Test is performed after results have been transferred from assay cards to the summary sheets. Consequently, no deletion notation appears on the former.

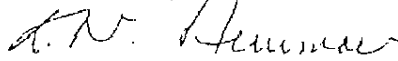
As you know, the Commission laboratory uses the Outrider Test to exclude cigarette analyses falling outside the 95% confidence limits. Of the 4,000 specimens tested in 1975, 160 (4%) were outside the established limit. This number falls within that percentage predicted for the test. As Prof. Arkin points out, this

"... is, no doubt, due to the 'inherent' variability of the agricultural product used (tobacco) and nature of the manufacturing process ... [giving rise] to individual wide variations ... from cigarette to cigarette."

To recapitulate, all resultant summary values for monitors must fall within prescribed limits ( $30/\sqrt{n}$ ). The Federal Trade Commission laboratory has been using these limits for some time and the use of these limits, as stated earlier, was reaffirmed by Dr. Spears at the January 1974 meeting. Results that fall outside these limits are discarded. This accounts for the "Deleted Day." The data questioned by Prof. Arkin on pages 7-10 do not fall beyond the established variations for monitor cigarettes. The "short term fluctuations" that Prof. Arkin speaks of on page 11 result from variation of the monitor cigarettes within acceptable limits.

We appreciate and welcome the Institute's continued surveillance of our cigarette laboratory operation. In my August 1975 letter we suggested that, if Prof. Arkin has made a similar analysis of the TITL facility, comparison of his observations might prove mutually beneficial. Noting that no significant differences are apparent when data independently obtained by the FTC laboratory is compared with that obtained by TITL, we conclude that the accuracy achieved is within the acceptable range.

Sincerely yours,

  
I. D. Steinman, Ph.D.  
Office of Scientific Affairs

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